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10/554,050	01/25/2006	Ji-Hyun Kim	Q90861	8300

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EXAMINER
VAKILI, ZOHREH

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/554,050	KIM ET AL.	
	Examiner	Art Unit	
	ZOHREH VAKILI	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) *1-5* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-6 are presented for examination.

Applicant's Amendment and Remarks filed April 6, 2009 has been received and entered into the present application. Accordingly, claims 1-5 are withdrawn. Claim 6 is pending and is herein examined on the merits.

Applicant's arguments, filed April 6, 2009, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 112 (New Matter) (Maintained)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession

of the claimed invention. Applicant adds new limitations to the claims that raise the issue of new matter. New matter issues are raised when Applicant includes limitations in the claims that he/she clearly did not have possession of at the time of invention. The silence of the disclosure regarding the term "consisting essentially of" is not sufficient to now claim such a limitation because nowhere in the disclosure has Applicant discussed the term "consisting essentially of" in the context of the claimed composition.

Claim Rejections - 35 USC § 103 (Maintained)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows: 1. Determining the scope and contents of the prior art. 2. Ascertaining the differences between the prior art and the claims at issue. 3.Resolving the level of ordinary skill in the pertinent art. 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spiegel (US Pub. No. 20040082657) and in view of Ingram (US Pub. No. 20020010141 A1).

Spiegel teaches the present invention is a method and composition for suppressing the appetite of a human being using L-theanine. The method comprises the step of orally administering a composition comprising an appetite-suppressing amount of L-theanine. The L-theanine composition used as an appetite suppressant in accordance with the invention can be provided in solid form or liquid form and can be further combined with one or more inert ingredients or one or more additional active ingredients. The appetite suppressant composition of the invention provides a natural way of suppressing the appetite of a human being without causing the side effects associated with conventional appetite suppressants (see abstract). The L-theanine and D-theanine can be included together in the appetite suppressant composition. The L-theanine used in the composition of the invention can be used in a pure form (at least 99% L-theanine), in more crude forms including 50% or more L-theanine, or can be

present as a tea extract (see paragraph 0009). With respect to the additional active ingredients, Exemplary fat metabolizers include chromium picolinate, L-cysteine and L-carnitine (see paragraph 15). The method according to claim 1, wherein the administering step comprises orally administering a composition comprising L-theanine and at least one additional appetite suppressant (see claim 9). The method according to claim 9, wherein the additional appetite suppressant is selected from the group consisting of caffeine, ephedrine, phenylpropanolamine (PPA), L-glutamine, L-glutamic acid and mazindol (see claim 10). The method according to claim 1, wherein said administering step comprises Administering L-theanine in an amount of from about 0.1 mg/kg body weight to about 10.0 mg/kg body weight per day (see claim 12). Regarding the administration of the effective amount of the compound it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the quantity of the compound for administration provided in a composition, according to the guidance set forth in Spiegel, to provide the desired isoflavone to be administered, wherein the effective amount is about 0.1 to about 10.0 mg/kg/day. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Ingram discloses a composition and method for controlling weight gain and/or inducing weight loss in an individual, particularly a human being, in need of such weight loss (see abstract). The present invention, therefore, provides a method of

suppressing weight gain, inducing weight loss, or imparting a feeling of gastric fullness in a subject in need thereof, comprising: administering to the subject an amount of at least one isoflavone sufficient to suppress weight gain, induce weight loss, or impart a feeling of gastric fullness in said subject. The presention invention is also directed to a composition for the treatment of obesity, suppressing weight gain, inducing weight loss, or imparting a feeling of gastric fullness in a subject in need thereof, comprising an isoflavone in an amount effective to treat obesity. The isoflavone may be a phytoestrogen selected from the group consisting of daidzein, **genistein**, formononetin and biochanin A (see paragraph 10). The method of claim 1, wherein the amount of isoflavone administered to the subject is in the range of about 5 to about 500 mg/day (see claim 4). Wherein the effective amount is from about 5 to about 500 mg/day (see claim13). Regarding the administration of the effective amount of the compound it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the quantity of the compound for administration provided in a composition, according to the guidance set forth in Ingram, to provide the desired isoflavone to be administered, wherein the effective amount is about 5 to about 500 mg/day. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Clearly, the skilled artisan is provided with ample instruction and motivation to use theanine, genisteine, L-carnitine, and caffeine to produce a composition that has

slimming effect. The skilled artisan is motivated to make compositions of the well known ingredients for medicinal and cosmetic uses, most notably for their anti-suppressant properties to offset the losing of weight by those who are in need of such a composition. The prior arts teach of the same component and its concentration that is instantly claimed. Accordingly, it is well settled that products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In other words, where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. See In reBest, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977).

In re Kerkhoven (205 USPQ 1069, CCPA 1980) states that "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the same purpose: the idea of combining them flows logically from their having been individually taught in the prior."

One of ordinary skill in the art would have been motivated to combine the above references and as combined teach and suggest the invention as claimed. Thus the claimed invention was within the ordinary skill in the art to make and use at the time the claimed invention was made and was as a whole, *prima facie* obvious.

Response to arguments

Applicant argues that adding the limitation "consisting essentially of" to claim 6 is not new matter and is supported in examples 5-8, figs 6 and 7, and page 7, lines 13-16. Examiner does not agree nowhere in the specification has been disclosed what the novel and unobvious character of the claimed invention is so as to define what would be excluded because of the consisting essentially wording. Applicant further argues that neither Spiegel nor Ingram teach catechin. Applicant's attention is directed to claim 6 where catechin is an optional component. Applicant also argues that neither references teach the removal of cellulite. Firstly, the preamble anti-cellulite in a composition claim is an intended use. Intended use does not have a patentable weight in a composition claim. Secondly, both references are directed to controlling weight gain by suppressing appetite. It is given and very obvious that any agent used to induce weight loss will naturally remove cellulite. As the body becomes more lean less cellulites are visible, because more fat is removed which is the cause of cellulites. Applicant points to the range of the claimed invention in an amount of 0.0001% to 20%. Firstly, the 0.0001% is almost zero that means almost one or all the components do not have to be present. Secondly both references teach at least 5 mg of any or all of the mentioned ingredients present is effective which meets the range of the claimed invention of 0.0001% to 20%. Applicant's remarks have been fully and carefully considered in their entirety, but fail to be persuasive.

For these reasons, and those already made of record at pages 2-8 of the previous Office Action dated January 7, 2009 of which such reasons are incorporated

herein by references, rejection of claim 5 remains proper and is **maintained**.

Conclusion

No claims of the present application are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Vakili whose telephone number is (571)-272-3099. The examiner can normally be reached on Monday-Friday (8:30 AM-5:00 PM). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zohreh Vakili May 7, 2009
Patent Examiner
Art Unit 1614

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614